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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SCHNIZER, RICHARD A	

ART UNIT	PAPER NUMBER
1635	

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John S. Pratt, Esq.
KILPATRICK STOCKTON LLP
1100 Peachtree St
Suite 2800
Atlanta, GA 30309-4530

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/919,504	EMANUELE ET AL.	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 March 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

An amendment was received and entered on 9/7/04.

Claims 1-42 remain pending and are under consideration in this Office Action.

Rejections/Objections Withdrawn

The rejection of claims 1-42 under 35 USC 112, second paragraph is withdrawn in view of Applicant's amendment substituting the word "and" for the word "to". The previous Action erroneously included in the heading for the rejection claims 2-7, 10-12, 18, 20-22, 28-30, 34-36, 39, 40, and 42. As indicated in the statement of the rejection, only claims 1, 8, 9, 13-17, 19, 23-27, 31-33, 37, 38, and 41 were indefinite. In any event, Applicant's amendment overcomes the rejection.

The objections to claims 33 and 38 are withdrawn are withdrawn in view of Applicant's amendments.

Priority

Applicant has claimed priority under 35 USC 120 to a variety of US patent applications including prior application 08/138,271 ('271). This priority claim cannot be granted for the following reasons. All instant claims embrace compositions comprising an octablock copolymer and a nucleic acid, however none of the priority documents provides support for this combination of limitations. For this reason, the filing date of the instant claims must be the filing date of the instant application, 7/31/01.

Response to Arguments

Applicants arguments filed 9/7/04 have been fully considered but are unpersuasive.

Applicant argues at pages 17 and 18 of the response that prior application 08/138,271 ('271) discloses nucleic acid sequences in combination with either linear copolymers or octablock copolymers. The essence of Applicant's argument is that the '271 application discloses nucleic acids in combination with copolymers of polyoxyethylene (POE) and polyoxypropylene (POP), and also discloses the non-patent reference Schmolka (J. Am. Oil Chemist Soc. 54:110-116(1977), which in turn teaches how to make a variety of copolymers from polyoxyethylene (POE) and polyoxypropylene (POP), including octablock copolymers, thereby providing support for the combination of octablock copolymers and nucleic acids. Applicant asserts that the Schmolka reference was incorporated into the '271 application "to provide disclosure for both linear **and** octablock copolymers in combination with nucleic acids." Emphasis in original. This assertion is supported only by the subsequent assertion that it was "apparent to applicants at the time of filing of the '271 application that their invention included the combination of linear polymers and nucleic acids **as well as** the combination of octablock copolymers and nucleic acids." Emphasis in original.

This argument is unpersuasive for the following reasons.

The Examiner agrees that Schmolka (1997) teaches how to make linear and octablock copolymers including poloxamers, meroxapols, poloxamines (i.e. octablock copolymers), and pluradot polyols. See Figs. 1-4. However, although Applicant asserts that the '271 application relied upon Schmolka for its disclosure of octablock copolymers, this assertion is not supported by evidence or logic. A review of the specification of '271 reveals that the invention claimed therein was directed to

admixtures of a therapeutic compound (e.g. a nucleic acid) and an effective amount of a block copolymer of the general formula:

$$HO(C_2H_4O)_bC_3H_6O)_a(C_2H_4O)_bH,$$

which is the general formula of a poloxamer, not an octablock copolymer. The specification of '271 does not appear to disclose or describe any copolymer other than a poloxamer, except by reference to Schmolka. At page 17, lines 1-6 the '271 specification indicates that the range of copolymers encompassed by the invention is shown in Fig.1. The Schmolka reference is referred to at page 17, lines 12-18, as providing a description of how to prepare the copolymers presented in Fig. 1. Fig. 1 discloses 21 copolymers, 17 of which are products of BASF corporation having trade names beginning with a prefix 'L', 'P', or 'F'. BASF corporation uses the prefix 'T' to denote octablock copolymers, so none of these 17 copolymers appears to be an octablock copolymer. The remaining 4 copolymers are CRL 336, CRL 1190, CRL 1235, and CRL 8950. There is nothing in the specification to suggest that any of these compounds is an octablock copolymer, and Applicant has provided no evidence or argument indicating such. In view of the available evidence, the specification of '271 is directed to poloxamers of the general formula:

$$HO(C_2H_4O)_bC_3H_6O)_a(C_2H_4O)_bH,$$

not to octablock copolymers, and the Schmolka reference provides guidance for to how to make the copolymers represented in Fig. 1 of '271, none of which is an octablock copolymer. Accordingly, there is no evidence or logical reason to support the conclusion that the '271 application disclosed a composition comprising octablock copolymers and nucleic acids. MPEP 608.01 (p) indicates that when incorporating material by reference "[p]articular attention should be directed to specific

portions of the referenced document where the subject matter being incorporated may be found." In this case, there is no reason to believe that the '271 application intended to rely upon Schmolka for disclosure of octablock copolymers because the '271 application does not mention the term "octablock" or indicate in any way that octablock copolymers are a part of the invention. On the contrary, the '271 application clearly indicates that the invention is directed to poloxamers of the general formula: $CO(C_2H_4O)_bC_3H_6O)_a(C_2H_4O)_bH$. For these reasons, the filing date of the instant claims must be the filing date of the instant application, 7/31/01.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 8-13, 16-23, 26-31, 33-36, 38, and 41 stand rejected under 35 U.S.C. 102(e) as being anticipated by Lemieux et al (US Patent 6,359,054, issued 3/19/02).

Lemieux teaches methods of delivering to an animal a composition comprising octablock block copolymers and nucleic acids, (see e.g. claim 13 at column 49). The nucleic acid can be an expression vector, antisense, ribozyme, or oligonucleotide (see column 21, lines 15-29). The octablock copolymers useful in the invention include a

variety of conventional and reverse orientation octablock copolymers set forth at column 15, lines 8-29, including Pluronics T1101, T1301, T1501 and T110R1, T130R1, and T150R1. Pluronic T1501 corresponds to the octablock copolymer recited in instant claims 1, 2, and 17-20, and comprises a hydrophobe weight of 7000 Da and hydrophobe percentage of 90. Pluronic T1301 corresponds to the copolymer in instant claims 3, 4, 21, and 22, and comprises a hydrophobe weight of 5500 Da and hydrophobe percentage of 90. Pluronic T1101 corresponds to the copolymer in instant claims 4 and 22, and comprises a hydrophobe weight of 4400 Da and hydrophobe percentage of 90. Pluronic T150R1 corresponds to the copolymer in instant claims 9, 10, 27, 28, 33, and 34, and comprises a hydrophobe weight of 6700 Da and hydrophobe percentage of 90. Pluronic T130R1 corresponds to the copolymer in instant claims 11, 12, 29, 30, 35, and 36, and comprises a hydrophobe weight of 5700 Da and hydrophobe percentage of 90. Pluronic T110R1 corresponds to the copolymer in instant claims 12, 30, and 36, and comprises a hydrophobe weight of 4800 Da and hydrophobe percentage of 90.

Thus Lemieux anticipates the claims.

Response to Arguments

Applicants arguments filed 4/15/04 have been fully considered but are unpersuasive. Applicant argues that Lemieux cannot be considered prior art because the effective filing date of the instant application is 10/15/93. This is unpersuasive for the reasons set forth above under Priority, i.e. the effective filing date of the instant application is 7/31/01. Applicant argues Lemieux fails to teach the molecular weight ranges of the copolymers as claimed. Applicant indicates that it is not clear what molecular weight is taught by Lemieux for each polymer, because no standard deviation

is given for each average molecular weight given. In response the PTO notes that the instant claims do not require any precise molecular weight, instead they are drawn to approximate hydrophobe molecular weights, e.g. "about 5220", "about 5750" or "about 6750". The instant specification does not define the term "about" in this context, so it has been given its broadest reasonable interpretation. Under this interpretation, the cited molecular weights of Lemieux, e.g. are deemed to meet the limitations of the claims. Applicant argues that no support is provided in Lemieux to expand the molecular weight ranges to encompass the instantly claimed ranges. This is unpersuasive, because the ranges of Lemieux need not be expanded in order to anticipate the claimed ranges. As indicated above, the claimed molecular weights and ranges are reasonably interpreted as embracing the molecular weights recited by Lemieux because they are not limited to any precise molecular weight, instead they are drawn to approximate molecular weights.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 6, 7, 9, 14, 15, 19, 24, 25, 27, 32, and 37 stand rejected under 35 U.S.C. 103(a) as being unpatentable over by Lemieux et al (US Patent 6,359,054, issued 3/19/02), and further in view of Emanuele (US Patent 5,674,911, issued 10/7/97).

Lemieux teaches methods of delivering to an animal a composition comprising emulsions of non-ionic block copolymers and nucleic acids. See e.g. claim 18. The copolymers are organized as octablocks (see e.g. claim 13 at column 49). The nucleic acid can be an expression vector, antisense, ribozyme, or oligonucleotide (see column 21, lines 15-29). The octablock copolymers useful in the invention include a variety of conventional and reverse orientation octablock copolymers set forth at column 15, lines 8-45 and 25-31, including Pluronics T1101, T1301, T1501 and T110R1, T130R1, and T150R1 (see column 14, lines 34-36 and 54-62). Pluronic T1501 corresponds to the octablock copolymer recited in instant claims 1, 6, 7, 19, 24, and 25. Pluronic T150R1 corresponds to the copolymer in instant claims 27, 32, and 37. Lemieux also teaches that the compositions may comprises TWEEN as a surfactant. See column 20, lines 43-47.

Lemieux does not teach a composition comprising both 0.1-5% by weight of a surfactant and 0.5-5% by volume of a low molecular weight alcohol.

Emanuele teaches that surfactants such as polyoxyethylenesorbitan (20) monooleate (TWEEN 80), and low molecular weight alcohols such as ethanol may be added to emulsions of non-ionic block copolymer compositions comprising nucleic acids. See column 11, lines 39-58. Further, the ethanol may be in the concentration range of 0.5-5% by volume, and the surfactant may be in a range of approximately 0.1-5% by weight. See e.g. claims 3, 5, and 6.

It would have been obvious to one of ordinary skill in the art at the time of the invention to add the surfactants and low molecular weight alcohols of Emanuele to the compositions of Lemieux. One would have been motivated to do so in order to stabilize the emulsions.

Claims 1, 2, 5, 8, 17-20, 23, 26, and 41 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Pahlson et al (Acta Pathol. Microl. Immunol. Scand. B (1986) 94(3): 117-125), in view of Woodard (Laboratory Animal Science (1989 May) 39(3): 222-225).

Pahlson teaches a method of inducing an immune response in a mouse by administering whole bacteria emulsified in Freund's complete adjuvant. See abstract. Whole bacteria are considered to comprise expression vectors (chromosomes) comprising sequences (promoters) that can alter the function of nucleic acids (coding sequences). Further, whole bacteria would also be considered to comprise ribozymes as part of their ribosomes, as well as antisense oligonucleotides (Okazaki fragments).

Pahlson does not teach an octablock copolymer.

Woodard teaches that the octablock copolymer T1501 is equivalent to Freund's complete adjuvant for the purpose of stimulating antibody production. See abstract.

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the T1501 octablock copolymer of Woodard for the Freund's complete adjuvant of Pahlson. One would have been motivated to do so because Woodard teaches that T1501 and Freund's complete adjuvant are equivalent in the art of stimulating antibody production. Regarding the obviousness of art-recognized equivalents, MPEP 2144.06 states in part:

> In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents... Smith v. Hayashi, 209 USPQ 754 (Bd. of Pat. Inter. 1980) (The mere fact that phthalocyanine and selenium function as equivalent photoconductors in the claimed environment was not sufficient to establish that one would have been obvious over the other. However, there was evidence that both phthalocyanine and selenium were known photoconductors in the art of electrophotography. "This, in our view, presents strong evidence of obviousness in substituting one for the other in an electrophotographic environment as a photoconductor." 209 USPQ at 759.).

> **An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious.** In re Fout, 675 F.2d 297, 213 USPQ 532 (CCPA 1982).

Emphasis added. Because T1501 and Freund's complete adjuvant are art-recognized equivalents in stimulating antibody production, it would have been obvious to substitute one for the other, even in the absence of an express suggestion to do so.

Therefore the invention as a whole was *prima facie* obvious.

Claims 3, 4, 9-13, 16, 21, 22, 27-31, 33, 35, 36, and 38 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Pahlson et al (Acta Pathol. Microl. Immunol. Scand. B (1986) 94(3): 117-125) and Woodard (Laboratory Animal Science (1989 May) 39(3): 222-225), as applied to claims 1, 2, 5, 8, 17-20, 23, 26, and 41 above, and further in view of Jansen et al (US Patent 4,902,500, issued 2/20/90).

The teachings of Pahlson and Woodard are summarized above, and can be combined to render obvious compositions comprising an octablock copolymer of instant claims 1, 2, 5, 8, 17-20, 23, and 26, and nucleic acids such as expression constructs, ribozymes, and antisense oligonucleotides.

Pahlson and Woodard do not teach the octablock copolymers of instant claims 3, 4, 9-13, 16, 21, 22, 27-31, 33, 35, 36, and 38.

Jansen teaches the following octablock copolymers:

Pluronic T1301, corresponding to the copolymer in instant claims 3 and 21.

Pluronic T1101 corresponding to the copolymer in instant claims 4 and 22.

Pluronic T150R1 corresponding to the copolymer in instant claims 9, 10, 13, 16, 27, 28, 31, 33, and 38.

Pluronic T130R1 corresponding to the copolymer in instant claims 11, 29, and

Pluronic T110R1 corresponding to the copolymer in instant claims 12, 30, and

It would also have been obvious to substitute the T1301, T1101, T150R1, T130R2, and T110R1 of Jansen for Freund's complete adjuvant in the invention of Pahlson. One would have been motivated to do so because these compounds have very close structural similarities to T1501, which is an art recognized functional equivalent of Freund's complete adjuvant, and would reasonably be expected to have similar performance characteristics.

Therefore the invention as a whole was *prima facie* obvious.

Claims 1-5, 8-13, 16-18, 20-22, 28-30, and 34-36 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Kabanov et al (US Patent 5,656,611, issued 8/12/97).

Kabanov teaches compositions comprising polynucleotides and octablock copolymers having molecular weights and relative amounts of POP and POE overlapping those of the instant claims. See abstract and column 7, line 23 to column 8, line 11, especially column 7, lines 40-50). The polynucleotides may be antisense, oligonucleotides, ribozymes, or expression vectors (see column 10, lines 9-28. The copolymers may be of standard or reversed orientation (see column 7, line 64 to column 8, line 3). The compositions of the copolymers, with respect to the amounts and proportions of POE and POP, embrace a wide variety of compounds (see e.g. column 7, lines 48-51 which disclose that POP and POE monomers may be present in each of the four octablock copolymers in amounts of from about 5 to about 400 monomers).

Kabanov does not teach the precise limitations of the claims with respect to the molecular weight of the POP portion of the copolymer, or the relative amounts of POP and POE in the copolymers. However, it would have been

obvious to one of ordinary skill in the art at the time of the invention to arrive at the compositions set forth in the claims in the process of optimizing the invention of Kabanov for the disclosed purpose of delivering nucleic acids to cells. Because the Kabanov teaches a range of compositions which overlaps or embraces those of the instant invention, Kabanov teaches the general conditions of the claims. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Thus the invention as a whole was *prima facie* obvious.

Claims 17, 39, 40, and 42 stand rejected under 35 U.S.C. 103(a) as being unpatentable over by Lemieux et al (US Patent 6,359,054, issued 3/19/02).

Lemieux teaches methods of delivering to an animal a composition comprising octablock block copolymers and nucleic acids, (see e.g. claim 13 at column 49). The nucleic acid can be an expression vector, antisense, ribozyme, or oligonucleotide (see column 21, lines 15-29). The octablock copolymers useful in the invention include a variety of conventional and reverse orientation octablock copolymers set forth at column 15, lines 8-29, including Pluronics T1101, T1301, T1501 and T110R1, T130R1, and T150R1, each of which has an average hydrophobe percentage of 90%.

Lemieux does not specifically exemplify an octablock copolymer with a hydrophobe percentage of greater than 90% and less than 95%. However, at column 15, line 60 to column 16, line 29, Lemieux teaches that the hydrophilic/hydrophobic character of the block copolymer can be optimized depending on the properties of the

agent to be delivered. Further, at column 13, lines 1-29, Lemieux teaches that the number of POE and POP monomers in each branch of the octablock may range from about 2 to about 800. Thus the molecular weight of the hydrophobic portion is a result effective variable that may be optimized over a range the encompasses that claimed by Applicant. As a result the invention as a whole was prima facie obvious.

Response to Arguments

Applicants arguments filed 4/15/04 have been fully considered but are unpersuasive.

Applicant argues at page 20 of the response that Lemieux and Emanuele are not prior art because they were filed after the claimed priority date of the instant application. This argument is unpersuasive for the reasons set forth above, i.e. the effective filing date of the instant claims is 7/31/01.

With respect to the rejections based on Pahlson and Woodard, Applicant argues at pages 20 and 21 of the response that it would not have been obvious to substitute the T1501 octablock copolymer of Woodward for the Freund's complete adjuvant of Pahlson because such substitution would have an impact on physical and biological interactions, and would affect the characteristics of the copolymer. This is unpersuasive because it is apparently an expression of opinion only, and lacks evidentiary support. It is unclear what specific impact would occur on physical and biological interactions, which physical and biological interactions would be impacted, and what would be the result of this impact. It is unclear what characteristics of T1501 would be affected, how they would be affected, and why they would be affected. As a result there is no reason to

conclude that one of ordinary skill in the art could not combine the cited teachings with a reasonable expectation of success. Applicant's discussion (bridging pages 20 and 21) of the differences in physical characteristics of various copolymers is irrelevant because the only copolymer cited in the rejection is T1501.

At page 21 of the response Applicant notes that Jansen teaches the inclusion of at least one phospholipid in the disclosed compositions, and Applicant argues the instant invention is not obvious over the combination of Jansen with Pahlson and Woodard because the instant claims do note recite any phospholipid. This is unpersuasive because the instant claims do not exclude the presence of any phospholipid, and the cited art teaches each and every limitation of the claims.

Applicant argues at pages 21 and 22 that Kabanov is not a proper prior art reference because the effective filing date of the instant application is 10/15/93. This is unpersuasive for the reasons set forth above e.g. under Priority. The effective filing date of the instant application is 7/31/01.

Applicant further argues at page 22 that Kabanov teaches compositions comprising a covalently modified polynucleotide, an octablock copolymer, and a polycationic homopolymer, copolymer or block copolymer, while the instant claims do not require a such a polycation. This is unpersuasive because the invention of Kabanov does not require such a combination either. See the abstract which states that the invention is a complex between a polynucleotide and a polyether block copolymer. While inclusion of a further polycationic polymer is preferable, it is not required. As a result there is no reason that one of ordinary skill in the art would not have arrived at the instant invention given the

teachings of Kabanov. Furthermore, the instant claims do not preclude the use of polycations, and Applicant has presented no evidence that the inclusion of polycations would affect the compositions in such a way that one of ordinary skill would not, through the process of optimization, arrive at compositions comprising the instantly claimed octablock copolymers.

For these reasons the rejections are maintained.

At page 22 Applicant argues that Lemieux is not a proper prior art reference because the effective filing date of the instant application is 10/15/93. This is unpersuasive for the reasons set forth above e.g. under Priority. The effective filing date of the instant application is 7/31/01.

Applicant argues Lemieux that there is no support in the specification to expand the molecular weight ranges of Lemieux to include an octablock copolymer with a hydrophobe percentage of greater than 90% and less than 95%. This is unpersuasive because at column 15, line 60 to column 16, line 29, Lemieux teaches that the hydrophilic/hydrophobic character of the block copolymer can be optimized depending on the properties of the agent to be delivered, and at column 13, lines 1-29, Lemieux teaches that the number of POE and POP monomers in each branch of the octablock may range from about 2 to about 800. Therefore Lemieux provides support for hydrophobe percentages in the range of 90%-95%, and is aware that this is a result effective variable. Applicant has presented no evidence to indicate that hydrophobe percentages in the range of 90%-95% provide unexpected results that would preclude a finding of obviousness.

For these reasons the rejections are maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, John Leguyader, be reached at 571-272-0760. The official central fax number is 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Richard Schnizer, Ph.D.

DAVE T. NGUYEN
PRIMARY EXAMINER